भारतीय मानक
Indian Standard

IS 23485 : 2019

(*ISO 13485 : 2016, ISO 16142-1 : 2016*
and ISO 16142-2 : 2017 NEQ)

चिकित्सा उपकरण — चिकित्सा उपकरणों के लिए गुणवत्ता प्रबंधन प्रणाली हेतु आवश्यकताएं एवं सुरक्षा और प्रदर्शन के आवश्यक सिद्धांत

Medical Devices — Quality Management System Requirements and Essential Principles of Safety and Performance for Medical Devices

ICS 11.20.01

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Hospital Planning Sectional Committee MHD 14

FOREWORD

0.1 General

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Hospital Planning Sectional Committee had been approved by the Medical Equipment and Hospital Planning Council.

This Indian Standard specifies requirements for a quality management system that can be used by an organization involved in one or more stages of the life-cycle of a medical device, including design and development, production, storage and distribution, installation, servicing and final decommissioning and disposal of medical devices, and design and development, or provision of associated activities (for example, technical support). The requirements in this Indian Standard can also be used by suppliers or other external parties providing product (for example, raw materials, components, subassemblies, medical devices, sterilization services, calibration services, distribution services, maintenance services) to such organizations. The supplier or external party can voluntarily choose to conform to the requirements of this Indian Standard or can be required by contract to conform.

Several jurisdictions have regulatory requirements for the application of quality management systems by organizations with a variety of roles in the supply chain for medical devices. Consequently, this Indian Standard expects that the organization:

a) Identifies its role(s) under applicable regulatory requirements;
b) Identifies the regulatory requirements that apply to its activities under these roles; and
c) Incorporates these applicable regulatory requirements within its quality management system.

The organization needs to understand how the definitions in this Indian Standard will be interpreted in light of regulatory definitions in the jurisdictions in which the medical devices are made available.

This Indian Standard can also be used by internal and external parties, including certification bodies, to assess the organization’s ability to meet customer and regulatory requirements applicable to the quality management system and the organization’s own requirements. It is emphasized that the quality management system requirements specified in this Indian Standard are complementary to the technical requirements for product that are necessary to meet customer and applicable regulatory requirements for safety and performance (Refer Section II of this standard)

The adoption of a quality management system is a strategic decision of an organization. The design and implementation of an organization’s quality management system is influenced by the:

a) Organizational environment, changes in that environment, and the influence that the organizational environment has on the conformity of the medical devices;
b) Organization’s varying needs;
c) Organization’s particular objectives;
d) Product the organization provides;
e) Processes the organization employs;
f) Organization’s size and organizational structure; and
g) Regulatory requirements applicable to the organization’s activities.

This standard is a merger of ISO 13485 : 2016 Medical devices — Quality management systems — Requirements for regulatory purposes, ISO 16142-1 : 2016 Medical Devices — Recognized essential principles of safety and performance of medical devices, Part 1 General essential principles and additional specific essential principles for all Non-IVD Medical Devices and Guidance on the Selection of Standards and ISO 16142-2 : 2017 Medical devices — Recognized essential principles of safety and performance of medical devices Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards. However, this national standard is not equivalent to these International Standards in technical content and structure and the changes have not been clearly identified.

(*Continued on third cover*)

Indian Standard

MEDICAL DEVICES — QUALITY MANAGEMENT SYSTEMS REQUIREMENTS

SECTION I

1 SCOPE

This Indian Standard specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Such organizations can be involved in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (for example, technical support). This Indian Standard can also be used by suppliers or external parties that provide product, including quality management system-related services to such organizations.

Requirements of this Indian Standard are applicable to organizations regardless of their size and regardless of their type except where explicitly stated. Wherever requirements are specified as applying to medical devices, the requirements apply equally to associated services as supplied by the organization.

The processes required by this Indian Standard that are applicable to the organization, but are not performed by the organization, are the responsibility of the organization and are accounted for in the organization's quality management system by monitoring, maintaining, and controlling the processes.

If applicable regulatory requirements permit exclusions of design and development controls, this can be used as a justification for their exclusion from the quality management system. These regulatory requirements can provide alternative approaches that are to be addressed in the quality management system. It is the responsibility of the organization to ensure that claims of conformity to this Indian Standard reflect any exclusion of design and development controls.

If any requirement in **Clauses 6, 7** or **8** of this Indian Standard is not applicable due to the activities undertaken by the organization or the nature of the medical device for which the quality management system is applied, the organization does not need to include such a requirement in its quality management system. For any clause that is determined to be not applicable, the organization records the justification as described in **4.2.2**.

2 NORMATIVE REFERENCES

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IS/ISO 9000 : 2015, *Quality management systems — Fundamentals and vocabulary.*

3 TERMS AND DEFINITIONS

For the purposes of this document, the terms and definitions given in IS/ISO 9000 : 2015 and the following apply.

3.1 Advisory Notice

Notice issued by the organization, subsequent to delivery of the medical device, to provide supplementary information or to advise on action to be taken in the:

a) Use of a medical device,
b) Modification of a medical device,
c) Return of the medical device to the organization that supplied it, or
d) Destruction of a medical device.

NOTE 1 — Issuance of an advisory notice can be required to comply with applicable regulatory requirements.

3.2 Authorized Representative

Natural or legal person established within a country or jurisdiction who has received a written mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's obligations under that country or jurisdiction's legislation.

[SOURCE: GHTF/SG1/N055 : 2009, 5.2]

3.3 Clinical Evaluation

Assessment and analysis of clinical data pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the manufacturer.

[SOURCE: GHTF/SG5/N4 : 2010, Clause 4]

3.4 Complaint

Written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety or performance of a medical device that has been released from the organization's control or related to a service that affects the performance of such medical devices.

NOTE 1 — This definition of 'complaint' differs from the definition given in IS/ISO 9000 : 2015.

3.5 Distributor

Natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user.

NOTE 1 — More than one distributor may be involved in the supply chain.

NOTE 2 — Persons in the supply chain involved in activities such as storage and transport on behalf of the manufacturer, importer or distributor, are not distributors under this definition.

[SOURCE: GHTF/SG1/N055 : 2009, 5.3]

3.6 Implantable Medical Device

Medical device which can only be removed by medical or surgical intervention and which is intended to:

a) Be totally or partially introduced into the human body or a natural orifice, or
b) Replace an epithelial surface or the surface of the eye, and
c) Remain after the procedure for at least 30 days.

NOTE 1 — This definition of implantable medical device includes active implantable medical device.

3.7 Importer

Natural or legal person in the supply chain who is the first in a supply chain to make a medical device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed.

[SOURCE: GHTF/SG1/N055 : 2009, 5.4]

3.8 Labelling

Label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents.

[SOURCE: GHTF/SG1/N70 : 2011, Clause 4]

3.9 Life-cycle

All phases in the life of a medical device, from the initial conception to final decommissioning and disposal.

[SOURCE: IS/ISO 14971 : 2007, 2.7]

3.10 Manufacturer

Natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s).

NOTE 1 — This 'natural or legal person' has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the medical devices in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority (RA) within that jurisdiction.

NOTE 2 — The manufacturer's responsibilities are described in other GHTF guidance documents. These responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.

NOTE 3 — 'Design and/or manufacture', as referred to in the above definition, may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabelling, sterilization, installation, or remanufacturing of a medical device; or putting a collection of devices, and possibly other products, together for a medical purpose.

NOTE 4 — Any person who assembles or adapts a medical device that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is not the manufacturer, provided the assembly or adaptation does not change the intended use of the medical device.

NOTE 5 — Any person who changes the intended use of, or modifies, a medical device without acting on behalf of the original manufacturer and who makes it available for use under his own name, should be considered the manufacturer of the modified medical device.

NOTE 6 — An authorized representative, distributor or importer who only adds its own address and contact details to the medical device or the packaging, without covering or changing the existing labelling, is not considered a manufacturer.

NOTE 7 — To the extent that an accessory is subject to the regulatory requirements of a medical device, the person responsible for the design and/or manufacture of that accessory is considered to be a manufacturer.

[SOURCE: GHTF/SG1/N055 : 2009, 5.1]

3.11 Medical Device

Instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

a) Diagnosis, prevention, monitoring, treatment or alleviation of disease;
b) Diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
c) Investigation, replacement, modification, or support of the anatomy or of a physiological process;
d) Supporting or sustaining life;
e) Control of conception;
f) Disinfection of medical devices;
g) Providing information by means of *in vitro* examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

NOTE 1 — Products which may be considered to be medical devices in some jurisdictions but not in others include:

a) Disinfection substances;
b) Aids for persons with disabilities;
c) Devices incorporating animal and/or human tissues;
d) Devices for *in vitro* fertilization or assisted reproduction technologies.

[SOURCE: GHTF/SG1/N071 : 2012, 5.1]

3.12 Medical Device Family

Group of medical devices manufactured by or for the same organization and having the same basic design and performance characteristics related to safety, intended use and function.

3.13 Performance Evaluation

Assessment and analysis of data to establish or verify the ability of an *in vitro* diagnostic medical device to achieve its intended use.

3.14 Post-market Surveillance

Systematic process to collect and analyse experience gained from medical devices that have been placed on the market.

3.15 Product

Result of a process.

NOTE 1 — There are four generic product categories, as follows:

a) Services (for example, transport);
b) Software (for example, computer program, dictionary);
c) Hardware (for example, engine mechanical part); and
d) Processed materials (for example, lubricant).

Many products comprise elements belonging to different generic product categories. Whether the product is then called service, software, hardware or processed material depends on the dominant element. For example, the offered product ‘automobile’ consists of hardware (for example, tyres), processed materials (for example, fuel, cooling liquid), software (for example, engine control software, driver’s manual), and service (for example, operating explanations given by the salesman).

NOTE 2 — Service is the result of at least one activity necessarily performed at the interface between the supplier and customer and is generally intangible. Provision of a service can involve, for example, the following:

a) An activity performed on a customer-supplied tangible product (for example, automobile to be repaired);
b) An activity performed on a customer-supplied intangible product (for example, the income statement needed to prepare a tax return);
c) The delivery of an intangible product (for example, the delivery of information in the context of knowledge transmission);
d) The creation of ambience for the customer (for example, in hotels and restaurants).

Software consists of information and is generally intangible and can be in the form of approaches, transactions or procedures.

Hardware is generally tangible and its amount is a countable characteristic. Processed materials are generally tangible and their amount is a continuous characteristic. Hardware and processed materials often are referred to as goods.

NOTE 3 — This definition of ‘product’ differs from the definition given in IS/ISO 9000 : 2015.

[SOURCE: IS/ISO 9000 : 2015, 3.4.2, modified]

3.16 Purchased Product

Product provided by a party outside the organization’s quality management system.

NOTE 1 — The provision of product does not necessarily infer a commercial or financial arrangement.

3.17 Risk

Combination of the probability of occurrence of harm and the severity of that harm.

NOTE 1 — This definition of ‘risk’ differs from the definition given in IS/ISO 9000 : 2015.

[SOURCE: ISO 14971 : 2007, 2.16]

3.18 Risk Management

Systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring risk.

[SOURCE: IS/ISO 14971 : 2007, 2.22]

3.19 Sterile Barrier System

Minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use.

[SOURCE: IS/ISO 11607-1 : 2006, 3.22]

3.20 Sterile Medical Device

Medical device intended to meet the requirements for sterility.

NOTE 1 — The requirements for sterility of a medical device can be subject to applicable regulatory requirements or standards.

4 QUALITY MANAGEMENT SYSTEM

4.1 General Requirements

4.1.1 The organization shall document a quality management system and maintain its effectiveness in accordance with the requirements of this Indian Standard and applicable regulatory requirements.

The organization shall establish, implement and maintain any requirement, procedure, activity or arrangement required to be documented by this Indian Standard or applicable regulatory requirements.

The organization shall document the role(s) undertaken by the organization under the applicable regulatory requirements.

NOTE — Roles undertaken by the organization can include manufacturer, authorized representative, importer or distributor.

4.1.2 The organization shall:

a) Determine the processes needed for the quality management system and the application of these processes throughout the organization taking into account the roles undertaken by the organization;

b) Apply a risk based approach to the control of the appropriate processes needed for the quality management system;

c) Determine the sequence and interaction of these processes.

4.1.3 For each quality management system process, the organization shall:

a) Determine criteria and methods needed to ensure that both the operation and control of these processes are effective;

b) Ensure the availability of resources and information necessary to support the operation and monitoring of these processes;

c) Implement actions necessary to achieve planned results and maintain the effectiveness of these processes;

d) Monitor, measure as appropriate, and analyse these processes;

e) Establish and maintain records needed to demonstrate conformance to this Indian Standard and compliance with applicable regulatory requirements (*see* **4.2.5**).

4.1.4 The organization shall manage these quality management system processes in accordance with the requirements of this Indian Standard and applicable regulatory requirements. Changes to be made to these processes shall be:

a) Evaluated for their impact on the quality management system;

b) Evaluated for their impact on the medical devices produced under this quality management system;

c) Controlled in accordance with the requirements of this Indian Standard and applicable regulatory requirements.

4.1.5 When the organization chooses to outsource any process that affects product conformity to requirements, it shall monitor and ensure control over such processes. The organization shall retain responsibility of conformity to this Indian Standard and to customer and applicable regulatory requirements for outsourced processes. The controls shall be proportionate to the risk involved and the ability of the external party to meet the requirements in accordance with **7.4.** The controls shall include written quality agreements.

4.1.6 The organization shall document procedures for the validation of the application of computer software used in the quality management system. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application.

The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software. Records of such activities shall be maintained (*see* **4.2.5**).

4.2 Documentation Requirements

4.2.1 *General*

The quality management system documentation (*see* **4.2.4**) shall include:

a) Documented statements of a quality policy and quality objectives;

b) A quality manual;

c) Documented procedures and records required by this Indian Standard;

d) Documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes;

e) Other documentation specified by applicable regulatory requirements.

4.2.2 *Quality Manual*

The organization shall document a quality manual that includes:

a) The scope of the quality management system, including details of and justification for any exclusion or non-application;

b) The documented procedures for the quality management system, or reference to them;

c) A description of the interaction between the processes of the quality management system.

The quality manual shall outline the structure of the documentation used in the quality management system.

4.2.3 *Medical Device File*

For each medical device type or medical device family, the organization shall establish and maintain one or more files either containing or referencing documents generated to demonstrate conformity to the requirement of this Indian Standard and compliance with applicable regulatory requirements.

The content of the file(s) shall include, but is not limited to:

a) General description of the medical device, intended use/purpose, and labelling, including any instructions for use;
b) Specifications for product;
c) Specifications or procedures for manufacturing, packaging, storage, handling and distribution;
d) Procedures for measuring and monitoring;
e) As appropriate, requirements for installation;
f) As appropriate, procedures for servicing.

4.2.4 *Control of Documents*

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in **4.2.5**.

A documented procedure shall define the controls needed to:

a) Review and approve documents for adequacy prior to issue;
b) Review, update as necessary and re-approve documents;
c) Ensure that the current revision status of and changes to documents are identified;
d) ensure that relevant versions of applicable documents are available at points of use;
e) Ensure that documents remain legible and readily identifiable;
f) Ensure that documents of external origin, determined by the organization to be necessary for the planning and operation of the quality management system, are identified and their distribution controlled;
g) Prevent deterioration or loss of documents;
h) Prevent the unintended use of obsolete documents and apply suitable identification to them.

The organization shall ensure that changes to documents are reviewed and approved either by the original approving function or another designated function that has access to pertinent background information upon which to base its decisions.

The organization shall define the period for which at least one copy of obsolete documents shall be retained. This period shall ensure that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record (*see* **4.2.5**), or as specified by applicable regulatory requirements.

4.2.5 *Control of Records*

Records shall be maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.

The organization shall document procedures to define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records.

The organization shall define and implement methods for protecting confidential health information contained in records in accordance with the applicable regulatory requirements.

Records shall remain legible, readily identifiable and retrievable. Changes to a record shall remain identifiable.

The organization shall retain the records for at least the lifetime of the medical device as defined by the organization, or as specified by applicable regulatory requirements, but not less than two years from the medical device release by the organization.

5 MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and maintenance of its effectiveness by:

a) Communicating to the organization the importance of meeting customer as well as applicable regulatory requirements;
b) Establishing the quality policy;
c) Ensuring that quality objectives are established;
d) Conducting management reviews;
e) Ensuring the availability of resources.

5.2 Customer Focus

Top management shall ensure that customer requirements and applicable regulatory requirements are determined and met.

5.3 Quality Policy

Top management shall ensure that the quality policy:

a) Is applicable to the purpose of the organization;
b) Includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system;
c) Provides a framework for establishing and reviewing quality objectives;
d) Is communicated and understood within the organization;
e) Is reviewed for continuing suitability.

5.4 Planning

5.4.1 *Quality Objectives*

Top management shall ensure that quality objectives, including those needed to meet applicable regulatory requirements and requirements for product, are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

5.4.2 *Quality Management System Planning*

Top management shall ensure that:

a) The planning of the quality management system is carried out in order to meet the requirements given in **4.1**, as well as the quality objectives;

b) The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, Authority and Communication

5.5.1 *Responsibility and Authority*

Top management shall ensure that responsibilities and authorities are defined, documented and communicated within the organization.

Top management shall document the interrelation of all personnel who manage, perform and verify work affecting quality and shall ensure the independence and authority necessary to perform these tasks.

5.5.2 *Management Representative*

Top management shall appoint a member of management who, irrespective of other responsibilities, has responsibility and authority that includes:

a) ensuring that processes needed for the quality management system are documented;

b) reporting to top management on the effectiveness of the quality management system and any need for improvement;

c) ensuring the promotion of awareness of applicable regulatory requirements and quality management system requirements throughout the organization.

5.5.3 *Internal Communication*

Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management Review

5.6.1 *General*

The organization shall document procedures for management review. Top management shall review the organization’s quality management system at documented planned intervals to ensure its continuing suitability, adequacy and effectiveness. The review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained (*see* **4.2.5).**

5.6.2 *Review Input*

The input to management review shall include, but is not limited to, information arising from:

a) Feedback;

b) Complaint handling;

c) Reporting to regulatory authorities;

d) Audits;

e) Monitoring and measurement of processes;

f) Monitoring and measurement of product;

g) Corrective action;

h) Preventive action;

j) Follow-up actions from previous management reviews;

k) Changes that could affect the quality management system;

m) Recommendations for improvement;

n) Applicable new or revised regulatory requirements.

5.6.3 *Review Output*

The output from management review shall be recorded (*see* **4.2.5**) and include the input reviewed and any decisions and actions related to:

a) Improvement needed to maintain the suitability, adequacy, and effectiveness of the quality management system and its processes;

b) Improvement of product related to customer requirements;

c) Changes needed to respond to applicable new or revised regulatory requirements;

d) Resource needs.

6 RESOURCE MANAGEMENT

6.1 Provision of Resources

The organization shall determine and provide the resources needed to:

a) Implement the quality management system and to maintain its effectiveness;

b) Meet applicable regulatory and customer requirements.

6.2 Human Resources

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

The organization shall document the process(es) for establishing competence, providing needed training, and ensuring awareness of personnel. The organization shall:

a) Determine the necessary competence for personnel performing work affecting product quality;

b) Provide training or take other actions to achieve or maintain the necessary competence;

c) Evaluate the effectiveness of the actions taken;

d) Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives;

e) Maintain appropriate records of education, training, skills and experience (*see* **4.2.5**).

NOTE — The methodology used to check effectiveness is proportionate to the risk associated with the work for which the training or other action is being provided.

6.3 Infrastructure

The organization shall document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. Infrastructure includes, as appropriate:

a) Buildings, workspace and associated utilities;

b) Process equipment (both hardware and software);

c) Supporting services (such as transport, communication, or information systems).

The organization shall document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. As appropriate, the requirements shall apply to equipment used in production, the control of the work environment and monitoring and measurement.

Records of such maintenance shall be maintained (*see* **4.2.5**).

6.4 Work Environment and Contamination Control

6.4.1 *Work Environment*

The organization shall document the requirements for the work environment needed to achieve conformity to product requirements.

If the conditions for the work environment can have an adverse effect on product quality, the organization shall document the requirements for the work environment and the procedures to monitor and control the work environment.

The organization shall:

a) Document requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could affect medical device safety or performance;

b) Ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are competent or supervised by a competent person.

NOTE — Further information can be found in ISO 14644 and ISO 14698.

6.4.2 *Contamination Control*

As appropriate, the organization shall plan and document arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product.

For sterile medical devices, the organization shall document requirements for control of contamination with microorganisms or particulate matter and maintain the required cleanliness during assembly or packaging processes.

7 PRODUCT REALIZATION

7.1 Planning of Product Realization

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system.

The organization shall document one or more processes for risk management in product realization. Records of risk management activities shall be maintained (*see* **4.2.5**).

In planning product realization, the organization shall determine the following, as appropriate:

a) Quality objectives and requirements for the product;

b) The need to establish processes and documents (*see* **4.2.4**) and to provide resources specific to the product, including infrastructure and work environment;

c) Required verification, validation, monitoring, measurement, inspection and test, handling, storage, distribution and traceability activities specific to the product together with the criteria for product acceptance;

d) Records needed to provide evidence that the realization processes and resulting product meet requirements (*see* **4.2.5**).

The output of this planning shall be documented in a form suitable for the organization’s method of operations.

NOTE — Further information can be found in ISO 14971.

7.2 Customer-related Processes

7.2.1 *Determination of Requirements Related to Product*

The organization shall determine:

a) Requirements specified by the customer, including the requirements for delivery and post-delivery activities;

b) Requirements not stated by the customer but necessary for specified or intended use, as known;

c) Applicable regulatory requirements related to the product;

d) Any user training needed to ensure specified performance and safe use of the medical device;

e) Any additional requirements determined by the organization.

7.2.2 *Review of Requirements Related to Product*

The organization shall review the requirements related to product. This review shall be conducted prior to the organization's commitment to supply product to the customer (for example, submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that:

a) Product requirements are defined and documented;

b) Contract or order requirements differing from those previously expressed are resolved;

c) Applicable regulatory requirements are met;

d) Any user training identified in accordance with **7.2.1** is available or planned to be available;

e) The organization has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained (*see* **4.2.5**). When the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

When product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

7.2.3 *Communication*

The organization shall plan and document arrangements for communicating with customers in relation to:

a) Product information;

b) Enquiries, contracts or order handling, including amendments;

c) Customer feedback, including complaints;

d) Advisory notices.

The organization shall communicate with regulatory authorities in accordance with applicable regulatory requirements.

7.3 Design and Development

7.3.1 *General*

The organization shall document procedures for design and development.

7.3.2 *Design and Development Planning*

The organization shall plan and control the design and development of product. As appropriate, design and development planning documents shall be maintained and updated as the design and development progresses.

During design and development planning, the organization shall document:

a) The design and development stages;

b) The review(s) needed at each design and development stage;

c) The verification, validation, and design transfer activities that are appropriate at each design and development stage;

d) The responsibilities and authorities for design and development;

e) The methods to ensure traceability of design and development outputs to design and development inputs;

f) The resources needed, including necessary competence of personnel.

7.3.3 *Design and Development Inputs*

Inputs relating to product requirements shall be determined and records maintained (*see* **4.2.5**). These inputs shall include:

a) Functional, performance, usability and safety requirements, according to the intended use; [as stipulated in Section II of this standard]

b) Applicable regulatory requirements and standards;

c) Applicable output(s) of risk management;

d) As appropriate, information derived from previous similar designs;

e) Other requirements essential for design and development of the product and processes.

These inputs shall be reviewed for adequacy and approved.

Requirements shall be complete, unambiguous, able to be verified or validated, and not in conflict with each other.

NOTE — Further information can be found in IEC 62366-1.

7.3.4 *Design and Development Outputs*

Design and development outputs shall:

a) Meet the input requirements for design and development;

b) Provide appropriate information for purchasing, production and service provision;
c) Contain or reference product acceptance criteria;
d) Specify the characteristics of the product that are essential for its safe and proper use.

The outputs of design and development shall be in a form suitable for verification against the design and development inputs and shall be approved prior to release.

Records of the design and development outputs shall be maintained (*see* **4.2.5**).

7.3.5 *Design and Development Review*

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned and documented arrangements to:

a) Evaluate the ability of the results of design and development to meet requirements;
b) Identify and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage being reviewed, as well as other specialist personnel.

Records of the results of the reviews and any necessary actions shall be maintained and include the identification of the design under review, the participants involved and the date of the review (*see* **4.2.5**).

7.3.6 *Design and Development Verification*

Design and development verification shall be performed in accordance with planned and documented arrangements to ensure that the design and development outputs have met the design and development input requirements.

The organization shall document verification plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size.

If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), verification shall include confirmation that the design outputs meet design inputs when so connected or interfaced.

Records of the results and conclusions of the verification and necessary actions shall be maintained (*see* **4.2.4** and **4.2.5**).

7.3.7 *Design and Development Validation*

Design and development validation shall be performed in accordance with planned and documented arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use.

The organization shall document validation plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size.

Design validation shall be conducted on representative product. Representative product includes initial production units, batches or their equivalents. The rationale for the choice of product used for validation shall be recorded (*see* **4.2.5**).

As part of design and development validation, the organization shall perform clinical evaluations or performance evaluations of the medical device in accordance with applicable regulatory requirements. A medical device used for clinical evaluation or performance evaluation is not considered to be released for use to the customer.

If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), validation shall include confirmation that the requirements for the specified application or intended use have been met when so connected or interfaced.

Validation shall be completed prior to release for use of the product to the customer.

Records of the results and conclusion of validation and necessary actions shall be maintained (*see* **4.2.4** and **4.2.5**).

7.3.8 *Design and Development Transfer*

The organization shall document procedures for transfer of design and development outputs to manufacturing. These procedures shall ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications and that production capability can meet product requirements.

Results and conclusions of the transfer shall be recorded (*see* **4.2.5**).

7.3.9 *Control of Design and Development Changes*

The organization shall document procedures to control design and development changes. The organization shall determine the significance of the change to function, performance, usability, safety and applicable regulatory requirements for the medical device and its intended use.

Design and development changes shall be identified. Before implementation, the changes shall be:

a) Reviewed;
b) Verified;
c) Validated, as appropriate;
d) Approved.

The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product in process or already delivered, inputs or outputs of risk management and product realization processes.

Records of changes, their review and any necessary actions shall be maintained (*see* **4.2.5**).

7.3.10 *Design and Development Files*

The organization shall maintain a design and development file for each medical device type or medical device family. This file shall include or reference records generated to demonstrate conformity to the requirements for design and development and records for design and development changes.

7.4 Purchasing

7.4.1 *Purchasing Process*

The organization shall document procedures (*see* **4.2.4**) to ensure that purchased product conforms to specified purchasing information.

The organization shall establish criteria for the evaluation and selection of suppliers. The criteria shall be:

a) Based on the supplier's ability to provide product that meets the organization's requirements;
b) Based on the performance of the supplier;
c) Based on the effect of the purchased product on the quality of the medical device;
d) Proportionate to the risk associated with the medical device.

The organization shall plan the monitoring and re-evaluation of suppliers. Supplier performance in meeting requirements for the purchased product shall be monitored. The results of the monitoring shall provide an input into the supplier re-evaluation process.

Non-fulfilment of purchasing requirements shall be addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements.

Records of the results of evaluation, selection, monitoring and re-evaluation of supplier capability or performance and any necessary actions arising from these activities shall be maintained (*see* **4.2.5**).

7.4.2 *Purchasing Information*

Purchasing information shall describe or reference the product to be purchased, including as appropriate:

a) Product specifications;
b) Requirements for product acceptance, procedures, processes and equipment;
c) Requirements for qualification of supplier personnel;
d) Quality management system requirements.

The organization shall ensure the adequacy of specified purchasing requirements prior to their communication to the supplier.

Purchasing information shall include, as applicable, a written agreement that the supplier notify the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements.

To the extent required for traceability given in **7.5.9**, the organization shall maintain relevant purchasing information in the form of documents (*see* **4.2.4**) and records (*see* **4.2.5**).

7.4.3 *Verification of Purchased Product*

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements. The extent of verification activities shall be based on the supplier evaluation results and proportionate to the risks associated with the purchased product.

When the organization becomes aware of any changes to the purchased product, the organization shall determine whether these changes affect the product realization process or the medical device.

When the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification activities and method of product release in the purchasing information.

Records of the verification shall be maintained (*see* **4.2.5**).

7.5 Production and Service Provision

7.5.1 *Control of Production and Service Provision*

Production and service provision shall be planned, carried out, monitored and controlled to ensure that product conforms to specification. As appropriate, production controls shall include but are not limited to:

a) Documentation of procedures and methods for the control of production (*see* **4.2.4**);
b) Qualification of infrastructure;
c) Implementation of monitoring and measurement of process parameters and product characteristics;
d) Availability and use of monitoring and measuring equipment;
e) Implementation of defined operations for labelling and packaging;
f) Implementation of product release, delivery and post-delivery activities.

The organization shall establish and maintain a record (*see* **4.2.5**) for each medical device or batch of medical devices that provides traceability to the extent specified in **7.5.9** and identifies the amount manufactured and amount approved for distribution. The record shall be verified and approved.

7.5.2 *Cleanliness of Product*

The organization shall document requirements for cleanliness of product or contamination control of product if:

a) Product is cleaned by the organization prior to sterilization or its use;
b) Product is supplied non-sterile and is to be subjected to a cleaning process prior to sterilization or its use;
c) Product cannot be cleaned prior to sterilization or its use, and its cleanliness is of significance in use;
d) Product is supplied to be used non-sterile, and its cleanliness is of significance in use;
e) Process agents are to be removed from product during manufacture.

If product is cleaned in accordance with a) or b) above, the requirements contained in **6.4.1** do not apply prior to the cleaning process.

7.5.3 *Installation Activities*

The organization shall document requirements for medical device installation and acceptance criteria for verification of installation, as appropriate.

If the agreed customer requirements allow installation of the medical device to be performed by an external party other than the organization or its supplier, the organization shall provide documented requirements for medical device installation and verification of installation.

Records of medical device installation and verification of installation performed by the organization or its supplier shall be maintained (*see* **4.2.5**).

7.5.4 *Servicing Activities*

If servicing of the medical device is a specified requirement, the organization shall document servicing procedures, reference materials, and reference measurements, as necessary, for performing servicing activities and verifying that product requirements are met.

The organization shall analyse records of servicing activities carried out by the organization or its supplier:

a) To determine if the information is to be handled as a complaint;
b) As appropriate, for input to the improvement process.

Records of servicing activities carried out by the organization or its supplier shall be maintained (*see* **4.2.5**).

7.5.5 *Particular Requirements for Sterile Medical Devices*

The organization shall maintain records of the sterilization process parameters used for each sterilization batch (*see* **4.2.5**). Sterilization records shall be traceable to each production batch of medical devices.

7.5.6 *Validation of Processes for Production and Service Provision*

The organization shall validate any processes for production and service provision where the resulting output cannot be or is not verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results consistently.

The organization shall document procedures for validation of processes, including:

a) Defined criteria for review and approval of the processes;
b) Equipment qualification and qualification of personnel;
c) Use of specific methods, procedures and acceptance criteria;
d) As appropriate, statistical techniques with rationale for sample sizes;
e) Requirements for records (*see* **4.2.5**);
f) Revalidation, including criteria for revalidation;
g) Approval of changes to the processes.

The organization shall document procedures for the validation of the application of computer software used in production and service provision. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications.

Records of the results and conclusion of validation and necessary actions from the validation shall be maintained (*see* **4.2.4** and **4.2.5**).

7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems

The organization shall document procedures (*see* **4.2.4**) for the validation of processes for sterilization and sterile barrier systems.

Processes for sterilization and sterile barrier systems shall be validated prior to implementation and following product or process changes, as appropriate.

Records of the results and, conclusion of validation and necessary actions from the validation shall be maintained (*see* **4.2.4** and **4.2.5).**

NOTE — Further information can be found in IS/ISO 11607-1 and IS/ISO 11607-2.

7.5.8 *Identification*

The organization shall document procedures for product identification and identify product by suitable means throughout product realization.

The organization shall identify product status with respect to monitoring and measurement requirements throughout product realization. Identification of product status shall be maintained throughout production, storage, installation and servicing of product to ensure that only product that has passed the required inspections and tests or released under an authorized concession is dispatched, used or installed.

If required by applicable regulatory requirements, the organization shall document a system to assign unique device identification to the medical device.

The organization shall document procedures to ensure that medical devices returned to the organization are identified and distinguished from conforming product.

7.5.9 *Traceability*

7.5.9.1 *General*

The organization shall document procedures for traceability. These procedures shall define the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained (*see* **4.2.5**).

7.5.9.2 *Particular requirements for implantable medical devices*

The records required for traceability shall include records of components, materials, and conditions for the work environment used, if these could cause the medical device not to satisfy its specified safety and performance requirements.

The organization shall require that suppliers of distribution services or distributors maintain records of the distribution of medical devices to allow traceability and that these records are available for inspection.

Records of the name and address of the shipping package consignee shall be maintained (*see* **4.2.5**).

7.5.10 *Customer Property*

The organization shall identify, verify, protect, and safeguard customer property provided for use or incorporation into the product while it is under the organization's control or being used by the organization. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (*see* **4.2.5**).

7.5.11 *Preservation of Product*

The organization shall document procedures for preserving the conformity of product to requirements during processing, storage, handling, and distribution. Preservation shall apply to the constituent parts of a medical device.

The organization shall protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution by:

a) Designing and constructing suitable packaging and shipping containers;
b) Documenting requirements for special conditions needed if packaging alone cannot provide preservation.

If special conditions are required, they shall be controlled and recorded (*see* **4.2.5**).

7.6 Control of Monitoring and Measuring Equipment

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

The organization shall document procedures to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

As necessary to ensure valid results, measuring equipment shall:

a) Be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to Indian or national measurement standards: when no such standards exist, the basis used for calibration or verification shall be recorded (*see* **4.2.5**);
b) Be adjusted or re-adjusted as necessary: such adjustments or re-adjustments shall be recorded (*see* **4.2.5**);
c) Have identification in order to determine its calibration status;
d) Be safeguarded from adjustments that would invalidate the measurement result;
e) Be protected from damage and deterioration during handling, maintenance and storage.

The organization shall perform calibration or verification in accordance with documented procedures. In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action in regard to the equipment and any product affected.

Records of the results of calibration and verification shall be maintained (*see* **4.2.5**).

The organization shall document procedures for the validation of the application of computer software used for the monitoring and measurement of requirements. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications.

Records of the results and conclusion of validation and necessary actions from the validation shall be maintained (*see* **4.2.4** and **4.2.5**).

NOTE — Further information can be found in IS/ISO 10012.

8 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed to:

a) Demonstrate conformity of product;

b) Ensure conformity of the quality management system;

c) Maintain the effectiveness of the quality management system.

This shall include determination of appropriate methods, including statistical techniques, and the extent of their use.

8.2 Monitoring and Measurement

8.2.1 *Feedback*

As one of the measurements of the effectiveness of the quality management system, the organization shall gather and monitor information relating to whether the organization has met customer requirements. The methods for obtaining and using this information shall be documented.

The organization shall document procedures for the feedback process. This feedback process shall include provisions to gather data from production as well as post-production activities.

The information gathered in the feedback process shall serve as potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes.

If applicable regulatory requirements require the organization to gain specific experience from post-production activities, the review of this experience shall form part of the feedback process.

8.2.2 *Complaint Handling*

The organization shall document procedures for timely complaint handling in accordance with applicable regulatory requirements.

These procedures shall include at a minimum requirements and responsibilities for:

a) Receiving and recording information;

b) Evaluating information to determine if the feedback constitutes a complaint;

c) Investigating complaints;

d) Determining the need to report the information to the appropriate regulatory authorities;

e) Handling of complaint-related product;

f) Determining the need to initiate corrections or corrective actions.

If any complaint is not investigated, justification shall be documented. Any correction or corrective action resulting from the complaint handling process shall be documented.

If an investigation determines activities outside the organization contributed to the complaint, relevant information shall be exchanged between the organization and the external party involved.

Complaint handling records shall be maintained (*see* **4.2.5**).

8.2.3 *Reporting to Regulatory Authorities*

If applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices, the organization shall document procedures for providing notification to the appropriate regulatory authorities.

Records of reporting to regulatory authorities shall be maintained (*see* **4.2.5**).

8.2.4 *Internal Audit*

The organization shall conduct internal audits at planned intervals to determine whether the quality management system:

a) Conforms to planned and documented arrangements, requirements of this Indian Standard, quality management system requirements established by the organization, and applicable regulatory requirements;

b) Is effectively implemented and maintained.

The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results.

An audit program shall be planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval and methods shall be defined and recorded (*see* **4.2.5**). The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

Records of the audits and their results, including identification of the processes and areas audited and the conclusions, shall be maintained (*see* **4.2.5**).

The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results.

NOTE — Further information can be found in IS/ISO 19011.

8.2.5 *Monitoring and Measurement of Processes*

The organization shall apply suitable methods for monitoring and, as appropriate, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

8.2.6 *Monitoring and Measurement of Product*

The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at applicable stages of the product realization process in accordance with the planned and documented arrangements and documented procedures.

Evidence of conformity to the acceptance criteria shall be maintained. The identity of the person authorizing release of product shall be recorded (*see* **4.2.5**). As appropriate, records shall identify the test equipment used to perform measurement activities.

Product release and service delivery shall not proceed until the planned and documented arrangements have been satisfactorily completed.

For implantable medical devices, the organization shall record the identity of personnel performing any inspection or testing.

8.3 Control of Nonconforming Product

8.3.1 *General*

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The organization shall document a procedure to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation and disposition of nonconforming product.

The evaluation of nonconformity shall include a determination of the need for an investigation and notification of any external party responsible for the nonconformity.

Records of the nature of the nonconformities and any subsequent action taken, including the evaluation, any investigation and the rationale for decisions shall be maintained (*see* **4.2.5**)

8.3.2 *Actions in Response to Nonconforming Product Detected before Delivery*

The organization shall deal with nonconforming product by one or more of the following ways:

a) Taking action to eliminate the detected nonconformity;
b) Taking action to preclude its original intended use or application;
c) Authorizing its use, release or acceptance under concession.

The organization shall ensure that nonconforming product is accepted by concession only if the justification is provided, approval is obtained and applicable regulatory requirements are met. Records of the acceptance by concession and the identity of the person authorizing the concession shall be maintained (*see* **4.2.5**).

8.3.3 *Actions in Response to Nonconforming Product Detected after Delivery*

When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity. Records of actions taken shall be maintained (*see* **4.2.5**).

The organization shall document procedures for issuing advisory notices in accordance with applicable regulatory requirements. These procedures shall be capable of being put into effect at any time. Records of actions relating to the issuance of advisory notices shall be maintained (*see* **4.2.5**).

8.3.4 *Rework*

The organization shall perform rework in accordance with documented procedures that takes into account the potential adverse effect of the rework on the product. These procedures shall undergo the same review and approval as the original procedure.

After the completion of rework, product shall be verified to ensure that it meets applicable acceptance criteria and regulatory requirements.

Records of rework shall be maintained (*see* **4.2.5**).

8.4 Analysis of Data

The organization shall document procedures to determine, collect and analyse appropriate data to demonstrate the suitability, adequacy and effectiveness of the quality management system. The procedures shall include determination of appropriate methods, including statistical techniques and the extent of their use.

The analysis of data shall include data generated as a result of monitoring and measurement and from other relevant sources and include, at a minimum, input from:

a) Feedback;
b) Conformity to product requirements;
c) Characteristics and trends of processes and product, including opportunities for improvement;
d) Suppliers;
e) Audits;
f) Service reports, as appropriate.

If the analysis of data shows that the quality management system is not suitable, adequate or effective, the organization shall use this analysis as input for improvement as required in **8.5**.

Records of the results of analyses shall be maintained (*see* **4.2.5**).

8.5 Improvement

8.5.1 *General*

The organization shall identify and implement any changes necessary to ensure and maintain the continued suitability, adequacy and effectiveness of the quality management system as well as medical device safety and performance through the use of the quality policy, quality objectives, audit results, post-market surveillance, analysis of data, corrective actions, preventive actions and management review.

8.5.2 *Corrective Action*

The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Any necessary corrective actions shall be taken without undue delay. Corrective actions shall be proportionate to the effects of the nonconformities encountered.

The organization shall document a procedure to define requirements for:

a) Reviewing nonconformities (including complaints);
b) Determining the causes of nonconformities;
c) Evaluating the need for action to ensure that nonconformities do not recur;
d) Planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;
e) Verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;
f) Reviewing the effectiveness of corrective action taken.

Records of the results of any investigation and of action taken shall be maintained (*see* **4.2.5**).

8.5.3 *Preventive Action*

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be proportionate to the effects of the potential problems.

The organization shall document a procedure to describe requirements for:

a) Determining potential nonconformities and their causes;
b) Evaluating the need for action to prevent occurrence of nonconformities;
c) Planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;
d) Verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;
e) Reviewing the effectiveness of the preventive action taken, as appropriate.

Records of the results of any investigations and of action taken shall be maintained (*see* **4.2.5**).

MEDICAL DEVICES — ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE OF MEDICAL DEVICES

SECTION II

1.0 SCOPE

This section of the standard identifies and describes the six general essential principles of safety and performance that apply to all medical devices, including IVD medical devices (*in vitro* diagnostic).

This section also identifies and describes the additional essential principles of safety and performance which need to be considered during the design and manufacturing process, which are relevant to Non-IVD medical devices as well as to IVD medical devices.

2.0 GENERAL

The essential principles of safety and performance are the general, high-level criteria that when met indicate that a medical device is safe and effective. Regulatory requirements expect that a medical device be safe and effective during its life-cycle and so conformity with the essential principles of safety and performance has to be achieved throughout the life-cycle of the medical device.

For the medical device manufacturer, this usually means that their medical device has to be:

a) Designed to be safe and effective, complying with the essential principles,

b) Manufactured to maintain the design characteristics,

c) Used in a way that maintains the design characteristics, and

d) In the case of findings while the medical device is in the post-production phase, there’s a need toevaluate the production and post-production information for relevancy to safety and effectiveness and a redesign might be needed to make the medical device compliant again with the essential principles.

3.0 ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE OF MEDICAL DEVICES

Medical device performance can include technical functions in addition to clinical effectiveness. Performance is easier to objectively measure and quantify than clinical effectiveness. Performance may be described as how well or accurately a medical device carries out its use(s) as intended by its manufacturer. For some medical devices, medical benefit or clinical effectiveness can only be determined by conducting clinical investigations carried out in human subjects. The manufacturer of a medical device is expected to design and manufacture a product that is safe and clinically effective throughout its life-cycle. This section describes fundamental design and manufacturing criteria, referred to as essential principles of safety and performance, to ensure this outcome. This section is structured to provide general essential principles that apply to all medical devices including IVD medical devices and additional essential principles of safety and performance that need to be considered during the design and manufacturing process.

Essential principles of safety and performance provide broad, high-level, criteria for design, production, and post-production (including post-market surveillance) throughout the life-cycle of all medical devices, ensuring their safety and performance. The concept of essential principles was developed by the Global Harmonization Task Force. The concept is intended to encourage convergence in the evolution of regulatory systems for medical devices.

3.1 General Essential Principles for all Medical Devices

3.1.1 The medical device should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training and the medical and physical conditions of intended users, they will perform as intended by the manufacturer and not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against benefits to the patient and are compatible with a high level of protection of health and safety. This shall include:

a) Reducing, as far as reasonably practicable and appropriate, the risk of use error due to the design of the medical device user interface and the environment in which the medical device is intended to be used (design for patient safety);

b) Consideration of the technical knowledge, experience, education and training and, where applicable, the medical and physical conditions of intended users (design for lay, professional, disabled or other users).

3.1.2 The solutions adopted by the manufacturer for the design and manufacture of the medical device should conform to safety principles, taking into account the generally acknowledged state of the art. When risk reduction is required, the manufacturer should control the risks so that the residual risk associated with each hazard is judged acceptable. The manufacturer should apply the following principles in the priority order listed:

a) Identify known or fore*see*able hazards and estimate the associated risks arising from the intended use and fore*see*able misuse;

b) Eliminate risks as far as reasonably practicable through inherently safe design and manufacture;

c) Reduce as far as reasonably practicable the remaining risks by taking adequate protection measures, including alarms or information for safety;

d) Inform users of any residual risk.

3.1.3 The medical device should achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that during normal conditions of use, they are suitable for their intended purpose.

3.1.4 The characteristics and performances referred to in essential principles at **3.1.1, 3.1.2** and **3.1.3** should not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the medical device, as indicated by the manufacturer, when the medical device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.

3.1.5 The medical device should be designed, manufactured and packaged in such a way that their characteristics and performances during their intended use will not be adversely affected by transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.

3.1.6 Any undesirable side-effect shall constitute an acceptable risk when weighed against the performances intended. All known and fore*see*able risks, and any undesirable effects, should be minimized and be acceptable when weighed against the benefits of the intended performance of the medical device during normal conditions of use.

3.2 Additional Essential Principles of Safety and Performance of non-IVD Medical Devices

3.2.1 *Clinical Evaluation*

For those medical devices, where a clinical evaluation is required, the clinical evaluation should review clinical data to establish that a favourable benefit-risk ratio exists for the medical device in the form of

- Clinical investigation reports,
- Literature reports/reviews, and
- Clinical experience.

NOTE — Content and format of a clinical evaluation report is specific to the authority having jurisdiction. [Further information can be found in IS/ISO 14155]

3.2.2 *Chemical, Physical, and Biological Properties*

3.2.2.1 The medical device should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in essential principles at **3.1**. Particular attention should be paid to the following:

a) The choice of materials used, particularly as regards toxicity and, where appropriate, flammability;

b) The compatibility between the materials used and biological tissues, cells, and body fluids taking account of the intended use of the medical device;

c) The choice of materials used reflecting, where appropriate, matters such as hardness, wear and fatigue strength;

d) Where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand.

3.2.2.2 The medical device should be designed, manufactured and packaged in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the medical device and to the patients, taking account the intended purpose of the product. Particular attention should be paid to the tissues exposed and to the duration and frequency of the exposure.

3.2.2.3 The medical device should be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures.

3.2.2.4 If the medical device is intended to administer medicinal products, they should be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and their performance and is maintained in accordance with the intended use.

3.2.2.5 The medical device should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks posed by substances that may leach or leak from the medical device. Special attention should be given to substances which are carcinogenic, mutagenic or toxic to reproduction.

3.2.3 *Infection and Microbial Contamination*

3.2.3.1 The medical devices and manufacturing processes should be designed in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate the risk of infection to patients, users and, where applicable, other persons. The design should:

a) Allow easy handling, and, where necessary,
b) Reduce as far as reasonably practicable and appropriate any microbial leakage from the medical device and/or microbial exposure during use, and
c) Prevent microbial contamination of the medical device or specimen, where applicable, by the patient, user or other person.

3.2.3.1 Medical devices labelled as having a special microbiological state should be designed, manufactured and packaged to ensure they remain so when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.

3.2.3.3 Medical devices delivered in a sterile state should be designed, manufactured and packaged in a non-reusable pack, and/or according to appropriate procedures, to ensure they are sterile when placed on the market and remain sterile, under the transport and storage conditions indicated by the manufacturer, until the protective packaging is damaged or opened.

3.2.3.4 Medical devices labelled either as sterile or as having a special microbiological state should have been processed, manufactured and, if applicable, sterilized by appropriate, validated methods.

3.2.3.5 Medical devices intended to be sterilized should be manufactured in appropriately controlled (for example, environmental) conditions.

3.2.3.6 Packaging systems for non-sterile medical devices should maintain the integrity and cleanliness of the product. If the medical devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system should be suitable taking account the method of sterilization indicated by the manufacturer. The labelling of the medical device should distinguish between identical or similar products sold in both sterile and non-sterile conditions.

3.2.3.7 For the medical devices incorporating a substance considered to be a medicinal product/drug, these essential principles are not intended to provide guidance on combination products as a whole since definitions have yet to be harmonized and practice varies between different jurisdictions. Where a medical device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product/drug as defined in the relevant legislation that applies in that jurisdiction and which is liable to act upon the body with action ancillary to that of the medical device, the safety, quality and performance of the medical device as a whole should be verified, as well as the safety, quality and efficacy of the substance in the specific application

3.2.3.8 When considering combination products as described in essential principle **3.2.3.7**, the non-medical device aspects (for example, substance, human blood derivative, ancillary substance) shall be assessed according to the requirements of the relevant authority having jurisdiction.

3.2.4 *Medical Devices Incorporating Materials of Biological Origin*

3.2.4.1 In some jurisdictions, products incorporating tissues, cells and substances of animal origin may be considered medical devices. In this case, such tissue, cells and substances should originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. National regulations may require that the manufacturer and/or the authority having jurisdiction maintain the information and the geographical origin of the animals. Processing, preservation, testing and handling of the tissue, cells and substances of animal origin should be carried out so as to provide optimal safety for patients, users and, by applicable, other persons. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

3.2.4.2 In some jurisdictions, products incorporating human tissues, cells and substances may be considered medical devices. In this case, the selection of sources, donors and/or substances of human origin, the processing, preservation, testing and handling of tissues, cells and substances of such origin should be carried out so as to provide optimal safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

3.2.4.3 In some jurisdictions, products incorporating cells and substances of microbial origin may be considered medical devices. In this case processing, preservation, testing and handling of cells and substances should be carried out so as to provide optimal safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

3.2.5 *Environmental Properties*

3.2.5.1 If the medical device is intended for use in combination with other medical devices or equipment the whole combination, including the connection system should be safe and should not impair the specified performance of the medical device. Any restrictions on use applying to such combinations should be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer or mechanical coupling, should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate risks from incorrect connection.

3.2.5.2 The medical device should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate:

a) The risks of injury to the patient, user or other persons in connection with their physical and ergonomic features,

b) The risks of use error due to the design of the medical device user interface and the environment in which the medical device is intended to be used,

c) The risks connected with reasonably fore*see*able external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature or variations in pressure and acceleration,

d) The risks associated with the use of the medical device when it comes into contact with materials, liquids, and gases to which it is exposed during normal conditions of use,

e) The risks associated with possible negative interaction between software and the environment within which it operates and interacts,

f) The risks of accidental penetration of substances into the medical device,

g) The risks of reciprocal interference with other medical devices normally used in the investigations or for the treatment given, and

h) The risks arising where maintenance or calibration are not possible (as with implants) from aging of materials used or loss of accuracy of any measuring or control mechanism.

3.2.5.3 The medical device should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate risks of fire or explosion during normal use and in single fault condition. Particular attention should be paid to a medical device whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.

3.2.5.4 The medical device should be designed and manufactured in such a way that adjustment, calibration, and maintenance, where such is necessary to achieve the performances intended, can be done safely.

3.2.5.5 The medical device should be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.

3.2.6 *Medical Devices with a Diagnostic or Measuring Function*

3.2.6.1 A diagnostic medical device or a medical device with a measuring function should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose of the medical device, based on appropriate scientific and technical methods.

3.2.6.2 The limits of accuracy should be indicated by the manufacturer.

3.2.6.3 Any measurement, monitoring and display scale should be designed in line with ergonomic principles, taking into account the intended purpose of the medical device.

3.2.6.4 Whenever possible values expressed numerically should be in commonly accepted, standardized units, and understood by users of the medical device. While generally supporting the convergence on the global use of internationally standardized measurement units, considerations of safety, user familiarity and established clinical practice may justify the use of other recognized measurement units.

3.2.7 *Protection Against Radiation*

3.2.7.1 *General:*

The medical device should be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation should be reduced as far as reasonably practicable and be appropriate for the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.

3.2.7.2 *Intended radiation:*

a) Where a medical device is designed to emit hazardous, or potentially hazardous, levels of visible and/or invisible radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it should be possible for the user to control the emissions. Such a medical device should be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.

b) Where a medical device is intended to emit potentially hazardous, visible and/or invisible radiation, they should be fitted, where reasonably practicable, with visual displays and/or audible warnings of such emissions.

3.2.7.3 *Unintended radiation:*

The medical device should be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as reasonably practicable and appropriate.

3.2.7.4 *Instructions for use:*

The operating instructions for a medical device emitting radiation should give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user, and on ways of avoiding misuse and of eliminating the risks inherent in installation.

3.2.7.5 *Ionizing radiation:*

a) A medical device intended to emit ionizing radiation should be designed and manufactured in such a way as to ensure that, where reasonably practicable and appropriate, the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use.

b) A medical device emitting ionizing radiation intended for diagnostic radiology should be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.

c) A medical device emitting ionizing radiation, intended for therapeutic radiology, should be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the energy distribution of the radiation beam.

3.2.8 *Medical Devices that Incorporate Software and Software as a Medical Device*

3.2.8.1 A medical device incorporating electronic programmable systems, including software, or software that is a medical device itself, should be designed to ensure repeatability, reliability and performance according to the intended use. In the event of a single fault condition, appropriate means should be adopted to eliminate or reduce as far as reasonably practicable and appropriate consequential risks.

3.2.8.2 For a medical device which incorporates software or for software that is a medical device itself, the software shall be validated according to the state of the art taking into account the principles of development life-cycle, risk management, verification and validation.

3.2.9 *Active Medical Devices and Devices Connected to the Medical Devices*

3.2.9.1 For an active medical device, in the event of a single fault condition, appropriate means should be adopted to eliminate or reduce as far as reasonably practicable and appropriate consequential risks.

3.2.9.2 The medical device, where the safety of the patient depends on an internal power supply, should be equipped with a means of determining the state of the power supply.

3.2.9.3 The medical device, where the safety of the patient depends on an external power supply, should include an alarm system to signal any power failure.

3.2.9.4 The medical device, intended to monitor one or more clinical parameters of a patient, should be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.

3.2.9.5 The medical device should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks of creating electromagnetic interference which could impair the operation of this or other medical devices or equipment in the usual environment.

3.2.9.6 The medical device should be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.

3.2.9.7 The medical device should be designed and manufactured in such a way as to avoid, as far as reasonably practicable and appropriate, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the medical device and in the event of a single fault condition in the medical device, provided that the medical device is installed and maintained as indicated by the manufacturer.

3.2.10 *Protection Against Mechanical Risks*

3.2.10.1 The medical device should be designed and manufactured in such a way as to protect the patient and user against mechanical risks for example, connected with resistance to movement, instability and moving parts.

3.2.10.2 The medical device should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate risks arising from vibration generated by the medical device, taking into account technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.

3.2.10.3 The medical device should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate risks arising from the noise emitted, taking account technical progress and the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.

3.2.10.4 Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate risks.

3.2.10.5 The medical device should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate, the risk of error when certain parts within the medical device are intended to be connected or reconnected before or during use.

3.2.10.6 Accessible parts of the medical device (excluding the parts or areas intended to supply heat or reach given temperatures) and its surroundings should not attain potentially dangerous temperatures under normal conditions of use.

3.2.11 *Protection Against the Risks Posed to the Patient by Energy Supplies or Substances*

3.2.11.1 A medical device for supplying the patient with energy or substances should be designed and manufactured in such a way that the delivered amount can be set and maintained accurately enough to assure the safety of the patient and of the user.

3.2.11.2 The medical device should be fitted with the means of preventing and/or indicating any inadequacies in the delivered amount which could pose a danger. The medical device should incorporate suitable means to prevent, as far as reasonably practicable and appropriate, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.

3.2.12 *Controls and Indicators*

3.2.12.1 The function of the controls and indicators should be clearly specified on the medical device.

3.2.12.2 Where the medical device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information should be understandable to the user and, as appropriate, the patient.

3.2.13 Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons

3.213.1 A medical device for use by lay persons should be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from the variation that can be reasonably be anticipated in the lay person‘s technique and environment. The information and instructions provided by the manufacturer should be easy for the lay person to understand and apply.

3.2.13.2 A medical device for use by lay persons should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate the risk of error during use by the lay person in the handling of the medical device and also in the interpretation of results.

3.2.13.3 A medical device for use by lay persons should, as far as reasonably practicable and appropriate, include a procedure by which the lay person can verify that, at the time of use, the product will perform as intended by the manufacturer.

3.2.14 *Label and Instructions for Use*

3.2.14.1 Each medical device should be accompanied by the information needed to use it safely and properly, and to ensure the intended performance, taking into account the training and knowledge of the potential users and to identify the manufacturer of the medical device. This information comprises the details and the data on the label and in the instructions for use. All this information should be easily understood.

3.2.14.2 If the intended purpose of the medical device is not obvious to the user, the manufacturer shall clearly state it on the label and in the instructions for use.

3.2.14.3 As far as practicable and appropriate, the information needed to use the medical device safely shall be set out on the medical device itself. If not practicable and appropriate, the information shall be on the individual packaging. If the medical device is not individually packaged, the information shall be set out in the leaflet supplied with one or more medical devices. Instructions for use shall be included in the packaging for every medical device.

3.2.14.4 Where appropriate, this information should take the form of symbols. Any symbol or identification colour used shall conform to the relevant standards. The symbols and colours shall be described in the documentation supplied with the medical device.

3.2.14.5 The label shall meet the requirements of the authority having jurisdiction and contain the following particulars:

a) The name or trade name and address of the manufacturer and where the manufacturer does not have an address within the locale, an authorized representative within the locale, to which the user can refer;

b) The details strictly necessary to identify the medical device and the contents of the packaging especially for the users;

c) Where appropriate, the word ‘sterile’;

d) Where appropriate, the batch code, preceded by the word ‘LOT’, or the serial number;

e) Where appropriate, an indication of the date by which the medical device should be used (for example, expiration date), in safety, expressed as the year and month;

f) Where appropriate, an indication that the medical device is for single use. A manufacturer’s indication of single use shall be consistent;

g) If the medical device is custom-made, the words ‘custom-made device’ or follow n) below;

h) If the medical device is intended for clinical investigations, the words ‘exclusively for clinical investigations’ or follow n) below;

j) Any special storage and/or handling conditions;

k) Any special operating instructions;

m) Any warnings and/or precautions to take;

n) Year of manufacture for an active medical device other than that covered by e). This indication may be included in the batch or serial number;

p) Where applicable, method of sterilization; and

q) Where applicable, other requirements from authorities having jurisdiction.

EXAMPLES Global Medical Device Nomenclature (GMDN), Unique Device Identifier (UDI), and Universal Medical Device Nomenclature System (UMDNS).

3.2.14.6 Wherever reasonable and practicable, the medical device and detachable components shall be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the medical device and detachable components.

3.2.14.7 Where appropriate, the instructions for use shall contain the following particulars:

a) The name or trade name and address of the manufacturer and where the manufacturer does not have an address within the locale, an authorized representative within the locale, to which the user can refer;

b) The details strictly necessary to identify the medical device and the contents of the packaging especially for the users;

c) Where appropriate, the word ‘STERILE’;

d) Where appropriate, an indication that the medical device is for single use. A manufacturer’s indication of single use shall be consistent;

e) If the medical device is custom-made, the words ‘custom-made device’ or follow t) below;

f) If the medical device is intended for clinical investigations, the words ‘exclusively for clinical investigations’ or follow t) below;

g) Any special storage and/or handling conditions;

h) Any special operating instructions;

j) Any warnings and/or precautions to take;

k) Where applicable, method of sterilization;

m) If the medical device shall be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct medical devices or equipment to use in order to obtain a safe combination;

n) All the information needed to verify whether the medical device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the medical device operate properly and safely at all times;

p) Where appropriate, information to avoid certain risks in connection with implantation of the medical device;

q) Information regarding the risks of reciprocal interference posed by the presence of the medical device during specific investigations or treatment;

r) The necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;

s) If the medical device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the medical device to be resterilized, and any restriction on the number of reuses. Where the medical device is supplied with the intention that it be sterilized before use, the instructions for cleaning and sterilization shall be such that, if correctly followed, the medical device will still comply with the requirements in essential principles. If in accordance with essential principle **3.2.14.3** no instructions for use are needed, the information shall be made available to the user upon request;

t) Details of any further treatment or handling needed before the medical device can be used (for example, sterilization, final assembly, etc.);

u) In the case of a medical device emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation;

v) Where applicable, other requirements from authorities having jurisdiction.

3.2.14.8 The date of issue or revision of the instructions for use relevant to the particular medical device.

3.2.14.9 The instructions for use shall also include details allowing the medical staff to brief the patient on any contraindications and any precautions to be taken for a medical device intended to be used by a lay person. These details should cover in particular:

a) Precautions to be taken in the event of changes in the performance of the medical device;
b) Precautions to be taken as regards exposure, in reasonably fore*see*able environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;
c) Adequate information regarding the medicinal product or products which the medical device in question is designed to administer, including any limitations in the choice of substances to be delivered;
d) Precautions to be taken against any special, unusual risks related to the disposal of the medical device;
e) Medicinal substances, or human blood derivatives incorporated into the medical device as an integral part in accordance with essential principle **3.2.3.7**;
f) Degree of accuracy claimed for a medical device with a measuring function.

3.3 Additional Essential Principles of Safety and Performance of IVD Medical Devices

3.3.1 *Performance evaluation including analytical performance and, where appropriate, clinical performance*

3.3.1.1 For an IVD medical device, a performance evaluation should be conducted. The performance evaluation should review analytical performance data and, where appropriate, clinical performance data in the form of any:

a) Scientific, peer-reviewed literature,
b) Performance study reports, and
c) Experience gained by routine diagnostic testing.

To establish that the IVD medical device achieves its intended performance during normal conditions of use and that the known and fore*see*able risks, and any undesirable effects, are minimized and acceptable when weighed against the benefits of the intended performance.

3.3.1.2 Clinical performance studies using specimens from human subjects should be carried out in accordance with the spirit of the Declaration of Helsinki. This includes every step in the clinical performance study from first consideration of the need and justification of the study to publication of the results. In addition, some countries may have specific regulatory requirements for informed consent.

NOTE — Content and format of a performance evaluation report is specific to the authority having jurisdiction.

3.3.2 *Chemical, Physical and Biological Properties*

3.3.2.1 The IVD medical device should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in essential principle at **3.1.6**. Particular attention should be paid to the possibility of impairment of analytical performance due to incompatibility between the materials used and the specimens or analyte (measurand) to be detected (such as biological tissues, cells, body fluids and microorganisms), taking account of its intended use.

3.3.2.2 The IVD medical device should be designed, manufactured and packaged in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the IVD medical device and to patients, taking account of the intended use of the IVD medical device.

3.3.2.3 The IVD medical device should be designed and manufactured in such a way as to reduce, appropriately the risks posed by substances that may leach or leak from the IVD medical device. Special attention should be given to substances, which are carcinogenic, mutagenic or toxic to reproduction.

3.3.2.4 The IVD medical device should be designed and manufactured in such a way as to reduce, appropriately the risks posed by the unintentional ingress or egress of substances into or from the IVD medical device taking into account the IVD medical device and the nature of the environment in which it is intended to be used.

3.3.3 *Infection and Microbial Contamination*

3.3.3.1 The IVD medical device and manufacturing processes should be designed in such a way as to eliminate or to prevent the risk of infection to user, professional or lay, or, where applicable, other person. The design should:

a) Allow easy and safe handling, and, where necessary;
b) Prevent any microbial leakage from the IVD medical device or microbial exposure during use; and
c) Prevent microbial contamination of the IVD medical device or specimen, where applicable, by the user, professional or lay or other person.

3.3.3.2 The IVD medical device labelled either as sterile or as having a special microbiological state should be designed, manufactured and packaged to ensure it remains so when placed on the market and remains so under the transport and storage conditions specified by the manufacturer until the protective packaging is damaged or opened.

3.3.3.3 The IVD medical device labelled either as sterile or as having a special microbiological state should have been processed, manufactured and, if applicable, sterilized by appropriate, validated methods.

3.3.3.4 The IVD medical device intended to be sterilized should be manufactured in appropriately controlled (for example, environmental) conditions.

3.3.3.5 Packaging systems for a non-sterile IVD medical device should maintain the integrity and cleanliness of the IVD medical device.

3.3.4 *IVD Medical Devices Incorporating Materials of Biological Origin*

These essential principles are not intended to provide guidance on combination products as a whole since definitions have yet to be harmonized and practice varies between different jurisdictions.

3.3.4.1 Where the IVD medical device include tissues, cells and substances originating from animals, the processing, preservation, testing and handling of tissues, cells and substances of animal origin should be carried out to provide optimal safety for user, professional or lay, or other person.

3.3.4.2 Safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain IVD medical devices if the activity of the virus and other transmissible agent are integral to the intended use of the IVD medical device or when such elimination or inactivation process would compromise the performance of the IVD medical device.

National regulations may require that the manufacturer or the authority having jurisdiction retain information on the geographical origin of the animals.

3.3.4.3 Where an IVD medical device includes human tissues, cells and substances, the selection of sources, donors or substances of human origin, processing, preservation, testing and handling of tissues, cells and substances of such origin should be carried out to provide optimal safety for user, professional or lay, or other person. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain IVD medical devices if the activity of the virus and other transmissible agent are integral to the intended use of the IVD medical device or when such elimination or inactivation process would compromise the performance of the IVD medical device.

3.3.4.4 Where an IVD medical device includes cells and substances of microbial origin, the processing, preservation, testing and handling of cells and substances should be carried out to provide optimal safety for user, professional or lay, or other person.

In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain IVD medical devices if the activity of the virus and other transmissible agent are integral to the intended use of the IVD medical device or when such elimination or inactivation process would compromise the performance of the IVD medical device.

3.3.5 *Environmental Properties*

3.3.5.1 If the IVD medical device is intended for use in combination with other medical devices or equipment, the whole combination, including the connection system should not impair the specified performance of the medical devices. Any restrictions on use applying to such combinations should be indicated on the label or in the instructions for use.

3.3.5.2 The IVD medical device should be designed and manufactured in such a way as to remove or reduce, appropriately the following:

a) The risk of injury to user, professional or lay, or other person in connection with their physical and ergonomic features;

b) The risk of use error due to the ergonomic features, human factors and the environment in which the IVD medical device is intended to be used;

c) The risks connected with reasonably fore*see*able external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, pressure, humidity, temperature or variations thereof;

d) The risks associated with the use of the IVD medical device when it comes into contact with materials, liquids and gases to which it is exposed during normal conditions of use;

e) The risk associated with the possible negative interaction between software and the environment within which it operates and interacts;

f) The risks of accidental penetration of substances into the IVD medical device;

g) The risk of incorrect identification of specimens/samples; and

h) The risks of reasonably fore*see*able interference with other medical devices such as carry over between IVD medical devices.

3.3.5.3 The IVD medical device should be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention should be paid to an IVD medical device whose intended use includes exposure to or use in association with flammable substances or substances that could promote combustion.

3.3.5.4 The IVD medical device should be designed and manufactured in such a way that adjustment, calibration and maintenance, where such is necessary to achieve the performance intended, can be done safely.

3.3.5.5 The IVD medical device should be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.

3.3.6 *Performance Characteristics*

3.3.6.1 The IVD medical device should be designed and manufactured in such a way that the performance characteristics support the intended use based on appropriate scientific and technical methods. In particular, where appropriate, the design should address sensitivity, specificity, accuracy, which results from trueness (bias) and precision (repeatability and reproducibility), control of known relevant interferences and limits of detection. These performance characteristics need to be maintained during the lifetime of the IVD medical device as indicated by the manufacturer.

3.3.6.2 Where the performance of an IVD medical device depends on the use of calibrators or control materials, the traceability of values assigned to such calibrators or control materials should be ensured through available reference measurement procedures or available reference materials of a higher order.

3.3.6.3 Wherever possible, values expressed numerically should be in commonly accepted, standardized units and understood by the users of the IVD medical device.

3.3.7 *Protection Against Radiation*

3.3.7.1 The IVD medical device should be designed, manufactured and packaged in such a way that exposure of user, professional or lay, or other person to the emitted radiation (intended, unintended, stray or scattered) is reduced as far as reasonably practicable and appropriate.

3.3.7.2 When the IVD medical device is intended to emit potentially hazardous, visible or invisible radiation, it should as far as reasonably practicable and appropriate be:

a) Designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled or adjusted; and
b) Fitted with visual displays or audible warnings of such emissions.

3.3.8 IVD medical devices that incorporate software and standalone IVD medical device software

3.3.8.1 For the IVD medical device, which incorporates software or for standalone software that is an IVD medical device in itself, the software shall be validated according to the state of the art taking into account the principles of development life-cycle, risk management, verification and validation.

3.3.9 *IVD Medical Devices Connected to, or Equipped with, An Energy Source*

3.3.9.1 The IVD medical device, where the safety of the patient depends on an internal power supply in the IVD medical device, should be equipped with a means of determining the state of the power supply.

3.3.9.2 The IVD medical device should be designed and manufactured in such a way as to reduce, appropriately the risks of creating electromagnetic interference which could impair the operation of this or other medical devices or equipment in the usual environment.

3.3.9.3 The IVD medical device should be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.

3.3.9.4 The IVD medical device should be designed and manufactured in such a way as to avoid, as far as reasonably practicable, the risk of accidental electric shocks to the user, professional or lay, or other person both during normal use of the IVD medical device and in the event of a single fault condition in the IVD medical device, provided the IVD medical device is installed and maintained as indicated by the manufacturer.

3.3.10 *Protection Against Mechanical and Thermal Risks*

3.3.10.1 The IVD medical device should be designed and manufactured in such a way as to protect the user, professional or lay, or other person against mechanical risks connected with, for example, resistance to movement, instability and moving parts.

3.3.10.2 Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection means shall be incorporated.

3.3.10.3 The IVD medical device should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from vibration generated by the IVD medical device, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.

3.3.10.4 The IVD medical device should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise particularly at source.

3.3.10.5 Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user, professional or lay, or other person should handle should be designed and constructed in such a way as to minimize all possible risks.

3.3.10.6 The IVD medical device should be designed and manufactured in such a way as to reduce to the lowest practicable level the risk of error when certain parts within the IVD medical device are intended to be connected or reconnected before or during use.

3.3.10.7 Accessible parts of the IVD medical device (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings should not attain potentially dangerous temperatures under normal use.

3.3.11 *Protection Against the Risks Posed by IVD Medical Devices for Self-testing*

3.3.11.1 The IVD medical device for self-testing should be designed and manufactured in such a way that it performs appropriately for its intended use taking into account the skills and the means available to lay persons and the influence resulting from variation that can reasonably be anticipated in the lay person's technique and environment. The information and instructions provided by the manufacturer should be easy for the lay person to understand and apply.

3.3.11.2 The IVD medical device for self-testing should be designed and manufactured in such a way as to reduce, as far as reasonably practicable, the risk of use error by the lay person in the handling of the IVD medical device and, if applicable, the specimen, and also in the interpretation of results.

3.3.11.3 The IVD medical device for self-testing should, where reasonably possible, include a procedure by which the lay person can verify that, at the time of use, the product will perform as intended by the manufacturer.

3.3.12 *General Requirements Regarding the Information Supplied by the Manufacturer*

3.3.12.1 Each IVD medical device shall be accompanied by the information needed to identify the IVD medical device and its manufacturer and communicate safety and performance related information to the user, professional or lay, or other person, as appropriate. This information should be easily understood. Such information may appear on the IVD medical device itself, on the packaging or in the instructions for use. The accompanying information shall meet the requirements of the authority having jurisdiction and contain the following particulars**.**

a) The medium, format, content, legibility and location of the label and instructions for use shall be appropriate to the particular IVD medical device, its intended use and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams. Some IVD medical devices may include separate information for the professional user and the lay person.

b) The information required on the label, shall be provided on the IVD medical device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit or on the packaging of multiple IVD medical devices. Where multiple IVD medical devices are supplied to a single user or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided.

c) In duly justified and exceptional cases, instructions for use may not be needed or may be abbreviated if the IVD medical device can be used safely and as intended by the manufacturer without any such instructions for use.

d) Labels shall be provided in a human-readable format but may be supplemented by machine-readable forms, such as radio-frequency identification (RFID) or bar codes.

e) When the IVD medical device is intended for professional use only, instructions for use may be provided to the user in non-paper format (for example, electronic), except when the IVD medical device is intended for near-patient testing.

f) Residual risks, which are required to be communicated to the user or other person, shall be included as limitations, contraindications, precautions or warnings in the information supplied by the manufacturer.

g) Where appropriate, this information should take the form of internationally recognized symbols. Any symbol or identification colour used shall conform to the accepted standards. The symbols and colours shall be described in the documentation supplied with the IVD medical device.

h) In the case of an IVD medical device containing a substance or a mixture which can be considered as being dangerous, taking account of the nature and quantity of its constituents and the form under which they are present, relevant hazard pictograms and labelling requirements shall apply. Where there is insufficient space to put all the information on the IVD medical device itself, the relevant hazard pictograms shall be put on the label and the other information required by that regulation shall be given in the instructions for use.

j) The provisions on the safety data sheet for any substance or mixtures shall apply unless all relevant information as appropriate is already made available by the instructions for use.

k) For a reagent derived from biological material, the source and, where applicable, a measure of its activity.

3.3.12.2 The label shall meet the requirements of the authority having jurisdiction and contain the following particulars:

a) The name or trade name of the IVD medical device;

b) The details strictly necessary for the user to identify the IVD medical device and, where it is not obvious for the user, the intended use of the IVD medical device;

c) The name or trade name and address of the manufacturer and where the manufacturer does not have an address within the locale, an authorized representative within the locale to which the user can refer;

d) An indication that the IVD medical device is for in vitro diagnostic use;

e) The batch code/lot number or the serial number of the IVD medical device and separate components preceded by the word LOT or SERIAL NUMBER or an equivalent symbol, as appropriate, or the equivalent;

f) Where applicable, the unique device identification (UDI);

g) An unambiguous indication of the date until when the IVD medical device, or any of its components, may be used safely, without degradation of performance, expressed at least as the year, the month and, where relevant, the day, in that order, or where there is no indication of the date until when it may be used safely, the year of manufacture. This year of manufacture may be included as part of the batch or serial number, provided the date is clearly identifiable;

h) Where relevant, an indication of the net quantity of contents, expressed in terms of weight, concentration, volume, numerical count, or any combination of these, or other terms which accurately reflect the contents of the package;

j) An indication of any special storage or handling condition that applies;

k) Where appropriate, an indication of the sterile state of the IVD medical device and the sterilization method or a statement indicating any special microbiological state or state of cleanliness;

m) Warnings or precautions to be taken that need to be brought to the immediate attention of the user, professional or lay, or other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use;

n) Where applicable, any particular operating instructions;

p) If the IVD medical device is intended for single use or single-patient use, an indication of that fact. A manufacturer's indication of single use or single-patient use shall be consistent for a model or type reference;

q) If the IVD medical device is intended for self-testing or near-patient testing, an indication of that fact;

r) If the IVD medical device is for 'performance evaluation only', an indication of that fact; and

s) Where an IVD medical device kit includes individual reagents and articles that can be made available as a separate IVD medical device, each such IVD medical device shall comply with the labelling requirements contained **3.3.12.2**.

3.3.12.3 The instructions for use shall meet the requirements of the authority having jurisdiction and contain the following particulars:

a) The name or trade name of the IVD medical device;

b) The IVD medical device's intended use:

    1) What is detected or measured and whether it is qualitative, quantitative or a combination of both,
    2) The operating principle,
    3) Its function (for example, screening, monitoring, diagnosis or support of diagnosis),
    4) The specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate,
    5) The type of specimen(s) required,
    6) The intended user and intended patient population, and
    7) The use environment;

c) An indication that the IVD medical device is for in vitro diagnostic use;

d) A description of the test principle;

e) Instructions from reception of the specimen to obtaining and analysing results to ensure that the IVD medical device performs as intended (for example, calibration, quality control, cleaning and disinfection);

f) A description of the reagents, calibrators and controls and any limitation upon their use (for example, suitable for a dedicated instrument only) if applicable,

g) A list of materials provided and a list of special materials or equipment required but not provided;

h) For IVD medical devices intended for use together with other medical devices, including IVD medical devices, or equipment:

    1) Information to identify such IVD medical devices or equipment, in order to obtain a safe combination, or

    2) Information on any known restrictions to combinations of medical devices, including IVD medical devices, and equipment;

j) An indication of any storage (for example, temperature, light, humidity, dust) or handling conditions which apply;

k) An indication of any operating (for example, temperature, light, humidity, dust) or handling conditions which apply;

m) Where relevant, any change in the shelf life following the first opening of the primary container, together with the storage conditions and stability of working solutions;

n) If the IVD medical device is supplied as sterile, an indication of its sterile state, the sterilization method and instructions in the event of the sterile packaging being damaged before use;

p) Information that allows the user to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the IVD medical device. This information shall cover, where appropriate:

    1) Warnings, precautions or measures to be taken in the event of malfunction of the IVD medical device or its degradation as suggested by changes in its appearance that may affect performance,

    2) Warnings, precautions or measures to be taken in regard to the exposure to reasonably fore*see*able external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity or temperature,

    3) Warnings, precautions or measures to be taken in regard to the risks of interference posed by the reasonably fore*see*able presence of the IVD medical device during diagnostic procedures, evaluations or therapeutic treatments (for example, electromagnetic interference emitted by the IVD medical device affecting other equipment),

    4) Precautions related to materials incorporated into the IVD medical device that are carcinogenic, mutagenic or toxic, or that have endocrine disrupting properties or that could result in sensitization or allergic reaction of the patient or user,

    5) If the IVD medical device is intended for single use or single-patient use, an indication of that fact. A manufacturer’s indication of single use or single-patient use shall be consistent for a model or type reference, and

    6) If the IVD medical device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, decontamination, packaging and, where appropriate, the validated method of re-sterilization. Information shall be provided to identify when the IVD medical device should no longer be reused, for example, signs of material degradation or the maximum number of allowable reuses;

q) Any warnings or precautions related to potentially infectious material that is included in the IVD medical device;

r) Where relevant, requirements for special facilities (for example, clean room environment) or special training (for example, radiation safety) or particular qualifications of the IVD medical device intended user;

s) Conditions for collection, handling and preparation of the specimen including additive and preservatives necessary to maintain the integrity of the specimen and recommended storage, handling or shipping instructions for the protection and maintenance of stability of the specimen, if appropriate;

s) Details of any preparatory treatment or handling of the IVD medical device before it is ready for use (for example, sterilization, final assembly, calibration, etc.);

t) The information needed to verify whether the IVD medical device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:

    1) Details of the nature, and frequency, of preventative and regular maintenance, including cleaning and disinfection,

    2) Identification of any consumable components and how to replace them,

    3) Information on any necessary calibration to ensure that the IVD medical device operates properly and safely during its intended lifetime, and

    4) Methods of mitigating the risks encountered by persons involved in installing, calibrating or servicing the IVD medical device;

u) Where relevant, recommendations for quality control procedures;

v) The metrological traceability of values assigned to calibrators and trueness-control materials, including identification of applicable reference materials or reference measurement procedures of higher order;

v) Assay procedure including calculations and interpretation of results and where relevant, if any, confirmatory testing is necessary;

w) Performance characteristics, to the extent necessary for the IVD medical device to be used safely and effectively [for example, clinical sensitivity, clinical specificity, positive predictive value, negative predictive value, accuracy which results from trueness (bias) and precision (repeatability, reproducibility), limits of detection and measurement range, including information needed for the control of known relevant interferences, limitations of the method and information about the use of available reference measurement procedures and materials by the user];

y) Where relevant, reference intervals;

z) Information on interfering substances or limitations (for example, visual evidence of hyperlipidaemia or haemolysis, age of specimen) that can affect the performance of the IVD medical device;

aa) Warnings or precautions to be taken in order to facilitate the safe disposal of the IVD medical device, its accessories, and the consumables used with it, if any. This information shall cover, where appropriate:

    1) Infection or microbial hazards (for example, consumables contaminated with potentially infectious substances of human origin),

    2) Environmental hazards (for example, batteries or materials that emit potentially hazardous levels of radiation), and

    3) Physical hazards (for example, explosion);

bb) The name, registered trade name or registered trade mark of the manufacturer and the address of his registered place of business at which he can be contacted and his location be established, together with a telephone number or fax number or website address to obtain technical assistance;

cc) Date of issue or revision of the instructions for use relevant to the particular IVD medical device;

dd) A notice to the user, professional or lay, that any serious incident that has occurred in relation to the IVD medical device should be reported to the manufacturer and the authority having jurisdiction where the IVD medical device was purchased or used; and

ee) Where an IVD medical device kit includes individual reagents and articles that can be made available as separate IVD medical devices, each such IVD medical device shall comply with the labelling requirements contained in **3.3.12.3**.

3.3.12.4 In addition, the instructions for use for the IVD medical device intended for self-testing or near-patient testing shall comply with the following:

a) Details of the test procedure, including any reagent preparation, specimen collection or preparation and information on how to run the test and read the results;

b) The results need to be expressed and presented in a way that is readily understood by the intended user;

c) Information needs to be provided with advice to the user on action to be taken (in case of positive, negative or indeterminate result), on the test limitations and on the possibility of false positive or false-negative result. Information shall also be provided as to any factors that can affect the test result (for example, age, gender, menstruation, infection, exercise, fasting, diet or medication);

d) For the IVD medical device intended for self-testing, the information provided shall include a statement clearly directing that the user should not take any decision of medical relevance without first consulting the appropriate healthcare professional; and

e) For the IVD medical device intended for self-testing used for the monitoring of an existing disease, the information shall specify that the patient should only adapt the treatment if he has received the appropriate training to do so.

(Continued from second cover)

0.2 Clarification of Concepts

In this Indian Standard, the following terms or phrases are used in the context described below.

a) When a requirement is qualified by the phrase ‘as appropriate’, it is deemed to be appropriate unless the organization can justify otherwise. A requirement is considered appropriate if it is necessary for:
   1) Product to meet requirements;
   2) Compliance with applicable regulatory requirements;
   3) The organization to carry out corrective action;
b) The organization to manage risks.
c) When the term ‘risk’ is used, the application of the term within the scope of this Indian Standard pertains to safety or performance requirements of the medical device as stipulated in Section II of this standard or meeting applicable regulatory requirements.
d) When a requirement is required to be ‘documented’, it is also required to be established, implemented and maintained.
e) When the term ‘product’ is used, it can also mean ‘service’. Product applies to output that is intended for, or required by, a customer, or any intended output resulting from a product realization process.
f) When the term ‘regulatory requirements’ is used, it encompasses requirements contained in any law applicable to the user of this Indian Standard (for example, statutes, regulations, ordinances or directives). The application of the term ‘regulatory requirements’ is limited to requirements for the quality management system and the safety or performance of the medical device as stipulated in Section II of this standard.

In this Indian Standard, the following verbal forms are used:

a) ‘Shall’ indicates a requirement;
b) ‘Should’ indicates a recommendation;
c) ‘May’ indicates a permission; and
d) ‘Can’ indicates a possibility or a capability.

Information marked as ‘NOTE’ is for guidance in understanding or clarifying the associated requirements.

0.3 Process Approach

This Indian Standard is based on a process approach to quality management. Any activity that receives input and converts it to output can be considered as a process. Often the output from one process directly forms the input to the next process.

For an organization to function effectively, it needs to identify and manage numerous linked processes. The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the ‘process approach.’

When used within a quality management system, such an approach emphasizes the importance of:

a) Understanding and meeting requirements;
b) Considering processes in terms of added value;
c) Obtaining results of process performance and effectiveness; and
d) Improving processes based on objective measurement.

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